

# **Exhibit B**

## **Part 1 of 3**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY	)	MDL DOCKET NO. 1456
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	Civil Action No. 01-12257-PBS
	)	
THIS DOCUMENT RELATES TO:	)	Hon. Patti B. Saris
<i>United States of America ex rel. Ven-A-Care</i>	)	
<i>of the Florida Keys, Inc., et al. v. Dey Inc.,</i>	)	
<i>et al.</i> , Civil Action No. 05-11084-PBS	)	

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In re: PHARMACEUTICAL INDUSTRY	)	MDL DOCKET NO. 1456
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	Civil Action No. 07-10248-PBS
	)	
THIS DOCUMENT RELATES TO:	)	Hon. Patti B. Saris
<i>United States of America ex rel. Ven-A-Care</i>	)	
<i>of the Florida Keys, Inc., et al. v. Boehringer</i>	)	
<i>Ingelheim Corporation, et al.</i>	)	Subcategory Case No:
<i>et al.</i> , Civil Action No. 05-11084-PBS	)	06-11337-PBS

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EXPERT REPORT OF  
STEPHEN W. SCHONDELMAYER, PHARM.D., PH.D.

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**STEPHEN W. SCHONDELMAYER, PHARM.D., PH.D.**

<b>I. QUALIFICATIONS AND BACKGROUND.....</b>	<b>4</b>
<b>II. SCOPE OF REPORT .....</b>	<b>8</b>
<b>III. SUMMARY OF FINDINGS.....</b>	<b>10</b>
<b>IV. OVERVIEW OF THE PHARMACEUTICAL MARKET.....</b>	<b>14</b>
<b>A. Channels of Distribution.....</b>	<b>15</b>
<b>B. Sources of Payment.....</b>	<b>20</b>
<b>V. OVERVIEW OF PHARMACEUTICAL PRICING.....</b>	<b>23</b>
<b>A. Elements and Attributes of Drug Pricing Terms.....</b>	<b>24</b>
<b>B. Description of Key Drug Pricing Terms.....</b>	<b>25</b>
<b>C. Definition and Determination of Estimated Acquisition Cost (EAC).....</b>	<b>30</b>
<b>D. Case Study of the Texas Vendor Drug Program .....</b>	<b>37</b>
<b>E. Sources of Variation in Drug Prices .....</b>	<b>38</b>
<b>1. Class of Trade Variations in Drug Prices.....</b>	<b>39</b>
<b>2. Drug Product Type Variations in Drug Prices .....</b>	<b>40</b>
<b>3. Geographic Variations in Drug Prices.....</b>	<b>42</b>
<b>F. Role of Commercial Drug Price Databases and Manufacturer Price Reporting .....</b>	<b>43</b>
<b>G. Roxane's Price Reporting Conduct and Impact on Medicaid and Medicare .....</b>	<b>47</b>
<b>H. Dey's Price Reporting Conduct and Impact on Medicaid and Medicare .....</b>	<b>51</b>
<b>I. Impact of Roxane and Dey Conduct on Medicaid and Medicare .....</b>	<b>57</b>
<b>VI. THE MEDICAID DRUG PROGRAM.....</b>	<b>63</b>
<b>A. Medicaid Drug Reimbursement.....</b>	<b>66</b>
<b>B. Medicaid Drug Rebate Program.....</b>	<b>68</b>
<b>C. Prescription Reimbursement Under the State Medicaid Drug Programs .....</b>	<b>79</b>
<b>D. Federal Upper Limits (FULs) and Maximum Allowable Costs (MACs).....</b>	<b>87</b>
<b>VII. THE MEDICARE PART B PROGRAM.....</b>	<b>89</b>
<b>A. Medicare Part B Drug Program .....</b>	<b>89</b>
<b>B. Sources of Growth in Medicare Part B Drug Expenditures.....</b>	<b>92</b>
<b>C. Payment for DME Drugs.....</b>	<b>93</b>

<b>VIII. IMPORTANCE OF MEDICAID AND MEDICARE TO PHARMACEUTICAL MANUFACTURERS AND OTHER TOPICS.....</b>	<b>94</b>
<b>A. The National Pharmaceutical Council and the NPC Medicaid Book.....</b>	<b>95</b>
<b>B. Price Disclosures of Relator .....</b>	<b>98</b>
<b>D. Government GAO and OIG Studies.....</b>	<b>100</b>
<b>IX. SUMMARY .....</b>	<b>102</b>

## **I. QUALIFICATIONS AND BACKGROUND**

1. I make this statement as an independent expert in pharmacy, pharmaceutical economics, and public policy. I hold the following positions and titles in the College of Pharmacy at the University of Minnesota; Head, Department of Pharmaceutical Care & Health Systems; Century Mortar Club Endowed Chair in Pharmaceutical Management and Economics; Professor of Pharmaceutical Management and Economics; and Director of the PRIME Institute. I hold a Bachelor of Science in Pharmacy (1974, University of Missouri-Kansas City), a Doctor of Pharmacy and Residency Certificate (1977, University of Kentucky), a Master of Arts in Public Administration (1979, Ohio State University) and a Doctor of Philosophy in Administrative and Social Sciences in Pharmacy (1984, Ohio State University). A list of my professional memberships, professional activities, research activities, publications and other scholarly activities, citation of work in public media, offices held in professional and scientific organizations, university administrative and service positions, honors and awards, and civic and community activities is contained in a copy of my most recent curriculum vitae, which is attached hereto as Attachment "1."

2. My experience related to pharmaceutical economics and public policy research spans more than 30 years. I am currently the director of the PRIME Institute at the University of Minnesota, which was established in 1991 to conduct research related to the management and economics of the pharmaceutical marketplace. Prior to accepting a position at the University of Minnesota, I directed the Pharmaceutical Economics Research Center (PERC) at Purdue University from the time the Center was established

in 1986 to 1991. PERC also engaged in research related to the economics of the pharmaceutical marketplace.

3. I was appointed by the United States Congress to the Prescription Drug Payment Review Commission, an 11-member independent Congressional commission that served as an advisory body to the U.S. Congress with respect to the outpatient drug program established by the Medicare Catastrophic Coverage Act of 1988.

4. I provided professional staff analysis for the Kentucky Drug Formulary Council, Department for Human Resources, Commonwealth of Kentucky from 1975 to 1977. The Kentucky Drug Formulary Council was the nation's first governmental body to establish a generic equivalence standard for determining whether or not brand and generic drug products could be considered as generic equivalents and, therefore, could be substituted for one another. This generic equivalence formulary preceded the FDA's Orange Book.

5. As an academic researcher, my principal areas of interest have included trends in the pharmaceutical marketplace at all levels, the structure and performance of pharmaceutical markets, competition between and among brand name and generic drugs, and the impact of generic competition, including generic entry into brand drug markets. I have also conducted research on medication use and expenditures by the elderly, drug coverage under health insurance plans, access and affordability of pharmaceutical products, in addition to pharmacoeconomic research and policy analysis related to all aspects of the pharmaceutical marketplace. I have performed pharmacoeconomic research for many organizations, including, among others, the U.S. Health Care Financing Administration (HCFA, now known as the U.S. Centers for Medicare and Medicaid Services (CMS)), the U.S. General Accounting Office (GAO, now known as

the U.S. Government Accountability Office), the U.S. Food & Drug Administration (FDA), the U.S. Congress's Office of Technology Assessment (OTA), pharmaceutical firms, professional societies, and various state governments and agencies. I have also led pharmaceutical research and policy projects at the international level for governments including Thailand, Singapore, Spain, Canada, Argentina, Venezuela, South Africa, South Korea, and Taiwan.

6. Based upon my experience in professional consulting and academic research, I have particular expertise in economic and public policy issues in the pharmaceutical marketplace. One of the major focuses of my research and work relates to the impact and role of generic drugs and generic competition. In this context, I am well versed in assessing the economic impact of generic competition on all levels of the pharmaceutical marketplace, including on the various channels of distribution and upon consumers, the behavior of brand manufacturers faced with generic competition, and the mechanisms by which generic competition is fostered and, by contrast, impeded. Another of the major focuses of my research and work relates to the reimbursement for prescription drugs under private and public insurance programs including Medicaid and Medicare. In this context, I am well versed in assessing the economic impact of reimbursement policies on all levels of the pharmaceutical market including providers, patients, and payers.

7. My research projects directly related to general issues in the pharmaceutical market, such as drug prices, competition, generic entry, pricing, market penetration, channels of distribution, the effects of generic competition on the market for originator drug products, and other economic and marketing issues, also are listed in my curriculum vitae (see Attachment "1").

8. My experience includes conduct of several studies specifically for the Centers for Medicare and Medicaid Services (CMS)—the federal agency that oversees both Medicare and Medicaid. Among the studies conducted for CMS or its predecessor agency (HCFA, the Health Care Financing Administration) are the following:

a. *Report to Congress on Manufacturers' Prices and Pharmacists' Charges for Outpatient Drugs Covered by Medicare* (Department of Health and Human Services, June 27, 1989, Stephen W. Schondelmeyer and Joseph Thomas);

b. *Impact of the Medicaid Drug Rebate Program on Expenditures, Utilization, and Access: Final Report* (Health Care Financing Administration, Contract # 500-92-0022, DO #3, April 1995, Stephen W. Schondelmeyer, Judy A. Johnson, Dong Churl Suh, George Wright, Ann Cherlow, Andrew Asher, Angela Schmitt, Portia DeFilippes, Jon B. Christianson, John Kralewski);

c. *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices* (CMS Contract # 500-00-0049, Task Order 1, August 30, 2004, Stephen W. Schondelmeyer and Marion V. Wrobel);

d. *Sales of Drugs and Biologicals to Large Volume Purchasers: Final Report* (CMS Contract #500-00-0049, Task Order 1, September 19, 2005, Marian V. Wrobel, Stephen W. Schondelmeyer, Susan Jureidini, Shuchita Agarwal, Rachel Sayko, A.C. Doyle);

e. *Case Study of the Texas Vendor Drug Program's Approach to Estimating Drug Acquisition Cost: Final Report* (CMS Contract # 500-00-

049, Task Order 1, September 26, 2005, Marian V. Wrobel, Stephen W. Schondelmeyer, Shuchita Agarwal, and Janice Cooper); and

f. *Evaluation of Pharmaceutical Pricing Under Medicare Drug Card: Final Report* (U.S. Dept. of Health & Human Services, Assistant Secretary for Planning and Evaluation, Task Order Contract #100-03-0106, November 16, 2006, Stephen W. Schondelmeyer, Margaret Artz, Shriram Parashuram, Lois Olinger, and Sarah Shoemaker).

9. A list of other cases in which I have testified as an expert at trial or by deposition is attached as Appendix B to my curriculum vitae (see Attachment “1”).

10. I am being compensated for my time spent working on this case at the rate of \$500.00 per hour for time spent testifying, or preparing for testimony, and \$350.00 per hour for all other time.

## **II. SCOPE OF REPORT**

11. I understand that this action was originally initiated by the plaintiff, Ven-A-Care of the Florida Keys, Inc. (“Ven-A-Care”). I further understand that the United States has intervened. The suit names Boehringer Ingelheim Corporation (BIC); Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI); Roxane Laboratories, Inc.; and Roxane Laboratories, Inc., n/k/a Boehringer Ingelheim Roxane, Inc. (collectively known as “Roxane”) as the Defendants. A separate suit names Dey, Inc., Dey L.P., Inc., and Dey L.P. (collectively known as “Dey”).

12. I have reviewed the United States’ Amended Complaints filed against Roxane and Dey. The Plaintiffs in the Roxane and the Dey cases allege, among other things, that “The

defendants have engaged in a fraudulent scheme that has caused the Medicaid and Medicare programs to pay excessive reimbursement to [defendants'] customers, including pharmacies, home care pharmacies, and other purchasers of [defendants'] products. In furtherance of this scheme, the defendants reported false, fraudulent and inflated drug prices for certain drugs [ ] to several price reporting compendia that the Medicare and Medicaid programs relied upon to set reimbursement rates for [defendants'] customers. ”

13. I have reviewed numerous documents, including some of defendants' business records provided as discovery responses in this case, certain documents and records of the state and federal Medicaid programs, certain documents of the Medicare program, various deposition testimony and exhibits, literature in the field of pharmaceutical economics, and other publicly available documents and sources. In addition to those sources specifically referred to in this Report, all materials I considered in formulating my opinions are being produced or identified with this report.

14. I have been asked to testify about the following subject matters: an overview of the pharmaceutical market; an overview of pharmaceutical pricing; a description of the federal-state Medicaid drug programs; a description of the Medicaid drug rebate program; a description of Medicare and its programs for covering prescription drugs; a review of Roxane's and Dey's price reporting to the state Medicaid programs and commercial price databases; and other topics related to pharmaceutical pricing and reimbursement. Specifically, I have been asked to render an opinion as to the processes of Medicaid and Medicare programs with respect to drug reimbursement and the role of

drug manufacturers, including Roxane and Dey, as price reporters in the Medicaid and Medicare pharmaceutical payment systems.

15. My opinions contained herein are based upon my review of the above-described documents, as well as upon my qualifications and 30 years of experience described above. I understand that discovery is ongoing in this case, and as always with an expert report, I reserve the right to amend and update my opinions based upon additional information that may be provided to me, including additional discovery, or that may become known to me by other appropriate means in the future.

### **III. SUMMARY OF FINDINGS**

16. This case involves Roxane and Dey and the prices they reported to the commercial databases, federal and state Medicaid programs, and Medicare. The time period covered for the Roxane case includes the period encompassed by the Complaint “from on or before 1996, and continuing through January 1, 2004, in the case of the Medicare program, and to the present in the case of the Medicaid program.” (See U.S. First Amended Complaint, Roxane.) I understand that for drugs other than ipratropium bromide, the court has limited the damage period for Roxane to start in 1999. The time period covered for the Dey case includes the period encompassed by the Complaint “from on or before December 31, 1992, and continuing through 2004, in the case of the Medicare program, and to the present in the case of the Medicaid program.” (See U.S. First Amended Complaint, Dey). The general substance of my opinions is briefly summarized here. The remainder of the report provides more detailed opinions and the bases for my opinions.

17. The bases for my opinions are the documents and testimony I have reviewed in this litigation, my education and experience as reflected in my curriculum vitae (Attachment 1) and my accumulated knowledge and understanding of the pharmaceutical industry, pharmacoeconomics, government health care policy, pharmaceutical reimbursement policies and practices, and other related areas.

18. The federal and state Medicaid programs, during the operative time frame, used pricing information reported by drug manufacturers, including Roxane and Dey, to calculate the estimated acquisition cost for a drug product as a means to reimburse for the ingredient cost of each prescription. In addition, the Medicare program has used pricing information reported by drug manufacturers, including Roxane and Dey, to the commercial price databases as the basis for formulaic calculations of Medicare payments to providers.

19. The prices reported by drug manufacturers, including Roxane and Dey, to the commercial drug price databases were used by all, or virtually all, state Medicaid programs as a basis for the formulaic calculation of the reimbursement amount for prescriptions provided to Medicaid recipients by pharmacies and providers. The state Medicaid programs then used this pricing information in a formula to determine, among other things, the lower of: (1) the estimated acquisition cost plus the dispensing fee, (2) the maximum allowable cost (MAC) or federal upper limit (FUL) amount plus a dispensing fee, or (3) the pharmacy's usual and customary charge to the general public for the prescription as reported by the pharmacy. Similarly, drug manufacturers' reported prices to commercial databases are used by the Medicare program and its Medicare

contractors in the formulaic calculation of the reimbursement amount for drugs provided to Medicare recipients by physicians, pharmacies, or other providers.

20. Drug manufacturers, including Roxane and Dey, were aware that the state Medicaid programs and Medicare based their ingredient cost reimbursements on manufacturers' reports of drug product prices to the commercial price databases. Drug manufacturers, including Roxane and Dey, were aware that state Medicaid programs intended to use the manufacturer reported prices to commercial price databases to estimate the prices "generally and currently paid by pharmacies" in the marketplace. This general intent of state Medicaid programs was published routinely in the annual volumes of the National Pharmaceutical Council's publication "Pharmaceutical Benefits Under State Medical Assistance Programs" (also referred to as the "NPC Medicaid Book"), and other places. Roxane through BIPI has been a member of the National Pharmaceutical Council throughout the entire period at issue in this case. Dey was also aware of, and has referenced, the National Pharmaceutical Council publications on Medicaid program reimbursement in internal documents and communications as far back as 1995. (Memo from Dey Laboratories to Beth Raider, Price Alert and Pharmacy Blue Book Update, May 30, 1995, attachment "Medicaid Rx Reimbursement Report, Drug Topics, February 6, 1995, Source: National Pharmaceutical Council.)

21. Drug product prices had been routinely reported by manufacturers to the drug price compendia, such as Blue Book (First DataBank), MediSpan, and Red Book during the time frame of this complaint. The prices reported by drug manufacturers to drug price compendia have traditionally had a predictable relationship to actual market prices generally and currently paid by pharmacies in the marketplace, except for instances

where a manufacturer for its own reasons chose to report prices with inflated relationships when compared to the actual prices that are generally and currently paid by pharmacies in the marketplace. This behavior of certain drug manufacturers has resulted in reported prices, such as AWP, WAC, and DP (as defined in paragraph 23), and their relationship to actual prices generally and currently paid by pharmacies in the marketplace, becoming inflated progressively over time.

22. Policymakers and both Medicaid and Medicare program administrators were unaware of the conduct of certain drug manufacturers whereby reported prices (i.e., AWP, WAC, DP and list prices) were inflated well beyond the actual prices in order to engineer an inflated price spread and to result in inflated reimbursement, including Medicaid and Medicare reimbursement. Such practices were brought to the attention of certain government officials by Ven-A-Care and have been examined over time by various government agencies.

23. To the extent that Roxane and Dey reported prices to the commercial drug price databases (i.e., the “average wholesale price” (AWP), the “wholesale acquisition cost” (WAC), the “direct price” (DP), list, catalog or book prices, and other price information) that were not actual prices, or predictably related to actual prices that Roxane and Dey knew were generally and currently paid by customers, then Roxane and Dey engaged in the conduct, described above, whereby some drug manufacturers have caused AWP, WAC, DP and other price reports to become decreasingly representative of actual prices generally and currently paid by pharmacies in the marketplace. This behavior has caused increases in Medicaid and Medicare reimbursement amounts that were unintended by, and unknown to, the Medicaid and Medicare drug programs.

24. As described later in this report, the reporting of inflated price information to the compendial sources (i.e., Blue Book, MediSpan, or Red Book), which Roxane and Dey knew would result in an inflated AWP being published, also led to the inflation of state Medicaid and Medicare reimbursement amounts, at least to the extent that Roxane's and Dey's reported prices (i.e., AWP's and/or WAC's) inflated the median amount in the AWP array for the drug products covered by a specific J-code. The Medicare carriers based their reimbursement levels for Medicare Part B drugs upon the median of the AWP's published in the Red Book for all, or a substantial period of time, covered by the complaint. This increased reimbursement amount has also occurred when state Medicaid programs base reimbursement for drug products upon the "J-code" payment level set by the Medicare carriers.

#### **IV. OVERVIEW OF THE PHARMACEUTICAL MARKET**

25. Prescription drugs are the most widely used method for treating medical and health-related conditions. In 1996, the total retail prescription sales<sup>1</sup> in the U.S. were reported to be about \$72 billion and, by 2006, total retail prescription sales had grown to nearly \$250 billion. The total number of outpatient prescriptions grew from 2.2 billion in 1996 to 3.4 billion in 2006 and with adjustment for mail order prescriptions (that is, 3 months supply per prescription counted as 3 one-month prescriptions) was equal to about 3.9 billion monthly prescriptions. This prescription volume represents about 13 prescriptions per person per year in the United States in 2006.

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<sup>1</sup> Total retail sales as defined by IMS Health includes outpatient prescription sales of independent pharmacies, traditional chain pharmacies, supermarket pharmacies, mass merchandiser pharmacies, and mail order pharmacies. [IMS Health data as reported by the National Association of Chain Drug Stores on its website (<http://www.nacds.org/wmspage.cfm?parm1=507>), May 7, 2007].

26. The expenditure on prescription drugs is a substantial share of the total national health expenditures. Outpatient prescription drugs accounted for about 10.1% of national health expenditures in 2005. [U.S. Department of Health & Human Services (DHHS), Office of the Actuary, National Health Accounts, 2004. Note: The health spending projections were based on the 2004 version of the NHE released in January 2006 with data for years from 2005 to 2015 projected]. However, when prescription drug spending in all other sectors of the national health accounts (i.e., hospitals, physicians and clinics, long term care, home health, dentists, managed care, active military and military retirees, public health service, 340B facilities, the Veterans Administration and other settings) is taken into account, the expenditure on prescription drugs is approximately 17.5% of national health expenditures.

27. Since before 1990, outpatient prescription drug expenditures have been growing at a rapid rate. The annual growth rate in prescription drug spending has been in double digits for nearly all of the 15-year period from 1991 to 2006. Outpatient prescription drug spending in the 1990s, and the first part of the present decade, has grown considerably faster than health care spending overall. [U.S. DHHS, Office of the Actuary, National Health Accounts, 2004 version, released January 2006].

#### **A. Channels of Distribution**

28. In a broad sense, the structure of the pharmaceutical market can be described by two major features: (1) the channels of distribution for prescription drugs, or how the drug products flow through the market, and (2) the sources of payment for prescription drugs, or how the dollars flow through the market. These two structural perspectives are discussed in one of my reports for the Centers for Medicare & Medicaid Services.

[Schondelmeyer, SW and Wrobel, MV, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, CMS Contract # 500-00-0049, Task Order 1, August 30, 2004, pp. 9-13].

29. First, regarding channels of distribution, there are three primary levels in the distribution channel: (1) manufacturer or marketer, (2) wholesaler, and (3) pharmacy or other provider. Each of these channels of distribution and its role in the market was described in my 2004 report to CMS titled *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*. [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp.9-11]. The following sections are excerpted from that report:

Channels of distribution for prescription drug products are the pathways that drug products follow from the pharmaceutical manufacturer to the patient who ultimately uses the medication. There are three primary levels in the distribution channel: (1) manufacturers, (2) wholesalers, and (3) providers. Manufacturers and marketers reported \$215.7 billion in revenue from prescription drugs in 2002. The flows of these drug products through various channels of distribution are depicted in Exhibit 4. [*Attachment 2 in this report*].

30. The role of manufacturers and marketers in the pharmaceutical market was also described in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 9-10] as follows:

The manufacturer level is the starting point for prescription drugs as they begin their movement through the various channels of distribution. Any firm that manufactures or sells a prescription drug in the United States must hold a new drug application (NDA) or an abbreviated new drug application (ANDA) issued by the U.S. Food & Drug Administration (FDA). However, other firms may market a prescription drug without holding either an NDA or an ANDA, if such a firm has entered into a licensing agreement with an NDA or ANDA holder.

Every firm that markets a prescription drug in the United States must register with the FDA to obtain a unique national drug code (NDC) number (11-digits) for each drug product marketed. The first part of the NDC, the labeler code (5-digits), uniquely identifies the firm marketing the drug product. The second segment, the product code (4-digits), identifies a specific strength, dosage form, and formulation for a given drug product. The third segment, the package code

(2-digits), identifies package sizes and package types (e.g., bulk, unit dose, or unit of use). Both the product and package codes are assigned by the firm and not by the FDA.

Manufacturers or marketers, who want to be assured that the Medicaid program will cover their drug products, must sign a national drug rebate agreement with the Secretary of the Department of Health and Human Services in order for states to receive federal funding for outpatient drugs dispensed to Medicaid patients. Not all NDC holders participate in the Medicaid Drug Rebate program. Approximately 544 pharmaceutical companies (or labelers) currently participate in the Medicaid Drug Rebate Program.

31. The role of wholesalers and distributors in the pharmaceutical market was described in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 10-11] as follows:

Manufacturers or marketers of prescription drugs most often sell their drug products to a middleman, or intermediate level, before the drug product reaches the pharmacy or physician that will provide the drug to the patient. National wholesalers are the primary intermediate level in the channel of distribution process accounting for 45.7 percent of prescription drugs (\$98.5 billion) in 2002, (see Exhibit 4) [*Attachment 2 in this report*]. Other intermediate channels of distribution include chain warehouses with 32.3 percent (\$69.8 billion) of the market, regional and specialty wholesalers with 9.3 percent (\$20.2 billion) of the market, and group purchasing organizations that usually contract with a wholesaler to perform the distribution function on their behalf. About 12.6 percent of prescription sales by drug manufacturers are made directly to providers (e.g., physicians or hospitals) or pharmacies.

The principal trade organization representing wholesalers in the United States is the Healthcare Distribution Management Association (HDMA). In 2002, the HDMA reported that there were more than 72 distributor companies operating approximately 242 distribution centers.<sup>2</sup> On average, these distribution centers handle more than 21,000 different healthcare items. More than one-half of the items distributed (about 11,000) are prescription pharmaceuticals and biologics, and the additional items include “over-the-counter and herbal products, health and beauty aids, medical and hospital supplies, durable medical equipment and home healthcare items.”<sup>3</sup> The three largest wholesalers (Cardinal Health, AmeriSource Bergen, and McKesson) each have about 32 percent of the national market and collectively account for 97 percent of the drug sales that flow through national wholesalers and 83 percent of all wholesalers (national, regional, and specialty). Wholesalers add a markup and fees to the manufacturer’s drug product cost to cover the cost of distribution and other services they provide. The total wholesaler gross margin averaged about 4.3 percent in 2002 with a

<sup>2</sup> Healthcare Distribution Management Association, *2002 HDMA Industry Profile and Healthcare Factbook*, 2002, p. xi.

<sup>3</sup> HDMA, *2002 HDMA Industry Profile and Healthcare Factbook*, 2002, p. xi.

range from 3.7 to 5.5 percent for the 25<sup>th</sup> and 75<sup>th</sup> percentile. These costs are added to the manufacturer's drug product cost and passed on to the pharmacy or provider purchasing through a wholesaler.

In addition to full-line national wholesalers, there are also regional and specialty wholesalers that handle just under 10 percent of manufacturer drug sales. Regional wholesalers are usually similar to the national full-line wholesalers, but they typically have only one or a few distribution centers limited to a relatively small geographic region. Specialty wholesalers, in contrast, may have a national market presence, but instead limit the types of drug products stocked to a very narrow set. Specialty wholesalers may focus on generic drugs, biological agents, or drugs for a specific therapeutic purpose such as oncology, dialysis, or HIV therapy. Specialty wholesalers may also focus on serving certain facility types such as long term care pharmacies, home health agencies, or hospice facilities.

Group purchasing organizations (GPOs) may act on behalf of a group of providers to negotiate price with drug manufacturers. Most group purchasing organizations, however, do not ever take possession of, or handle, the drug product. Instead, GPOs often will contract with a traditional wholesaler to perform the wholesaling and distribution function on behalf of the GPO and its members.

A number of large chain pharmacies have developed and operate their own distribution centers rather than purchasing drug products through traditional wholesalers. Chain warehouses accounted for 32.3 percent (\$69.8 billion) of all prescription drug sales by drug manufacturers in 2002. Chains that operate their own warehouses incur expenses similar to those seen by traditional wholesalers (range from 3.7 to 5.5 percent). When a chain pharmacy performs the warehousing function in addition to the retail distribution and counseling functions, the chain does have additional costs similar to those that a wholesaler would have added to the manufacturer's drug product cost.

32. The role of pharmacies and providers in the pharmaceutical market was described in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 11] as follows:

The final step in the channel of distribution for pharmaceuticals comes when the pharmacist or physician provides the drug to the patient. In most cases, except for mail order pharmacies, this provision of the drug to the patient results from a face-to-face encounter with the patient. In addition to providing the drug product, the pharmacist is also responsible for taking steps to assure safe and effective drug use such as: development of a patient profile to screen for drug interactions, contraindications, and duplicate therapy; counseling the patient on appropriate use; and other similar activities. The physician has similar responsibilities and, in most Part B cases, administers the drug in conjunction with other services.

There are a number of types of pharmacies and providers as shown in Exhibit 4 [*Attachment 2 in this report*]. Community-based pharmacies accounted for the largest share (52.6 percent or \$113.3 billion) of manufacturer prescription drug sales in 2002. Community pharmacy includes traditional chain pharmacies (e.g., Walgreen's or CVS), mass merchant pharmacies (e.g., Wal-Mart or K-Mart), food and drug pharmacies (e.g., Kroger or Safeway), and independent pharmacies (i.e., locally-owned corner drug stores). Mail order pharmacies accounted for 13.3 percent (\$28.7 billion) of manufacturer prescription drug sales in 2002.

Health plan pharmacies purchased only 1.0 percent (\$2.3 billion) of all prescription drugs sold by manufacturers. These purchases were made by managed care plans (HMOs and PPOs) with their own in-house pharmacies where the health plan takes possession of drug product inventory and dispenses prescriptions directly to patients. The vast majority of managed care plans contract with a network of community pharmacies for provision of prescription drugs or with a pharmacy benefit manager (PBM) to administer the benefit for the managed care plan.

Other endpoints to the channels of distribution include: clinics and physicians' offices (1.0 percent; \$2.3 billion); long term care pharmacies (4.4 percent; \$9.5 billion); hospital pharmacies (15.9 percent; \$34.3 billion); and government facilities and other government programs (4.4 percent; \$9.6 billion).

33. The role of physician-administered drugs in the pharmaceutical market was described, in part, in my 2005 report to CMS titled *Sales of Drugs and Biologicals to Large Volume Purchasers: Final Report* [*Sales of Drugs and Biologicals to Large Volume Purchasers: Final Report* (CMS Contract #500-00-0049, Task Order 1, September 19, 2005, Marian V. Wrobel, Stephen W. Schondelmeyer, Susan Jureidini, Shuchita Agarwal, Rachel Sayko, A.C. Doyle), p. 17]. This study for CMS examined the purchasing patterns for the top 25 drug products covered by Medicare Part B. These 25 top drug products accounted for nearly two-thirds (63%) of the Medicare Part B drug expenditures in 2003. The market share by class of trade (type of purchaser) was determined for each of the 25 top Medicare Part B covered drug products. A summary of the findings was as follows:

Clinics or hospitals were the primary purchasers of doses in 22 of the 25 study HCPCs during the third quarter of 2004 (Exhibit 4.1). In addition, sales were typically split between the clinic and the hospital classes of trade. For 20 of the

25 drugs, both the clinic and the hospitals (sic) classes of trade each had at least ten percent of total sales.

The retail classes of trade were the primary purchasers of drug products in two of the three remaining HCPCs. Federal facilities were the primary purchaser of drug products in the third remaining HCPC code. Mail service pharmacies, HMOs, home health care and long term care facilities were never primary purchasers for any of these 25 drugs.

34. Durable medical equipment (DME) providers serve a unique role in the distribution of certain types of drug products. The certain drug products referred to here are those drug products that are typically administered by, or in conjunction with, durable medical equipment such as inhalation devices, infusion pumps, patient-controlled analgesic devices, or other types of medical equipment. These drugs are sometimes referred to as DME drugs and, for eligible patients, they are covered under the outpatient services component of the Medicare program known as Medicare Part B or under Medicaid.

35. DME drugs are mostly inhalation and injectable drugs used to treat certain medical conditions such as various types of respiratory conditions, infectious diseases, and severe pain.

#### **B. Sources of Payment**

36. There are three basic sources of payment for prescriptions: (1) self-pay or cash-pay individuals, (2) private third party insurance coverage, and (3) public (government) third party insurance coverage. The role of each source of payment in the prescription drug market was described in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 11] as follows:

Payments for prescription drug products may come from one, or more, sources including: the patient as an individual (termed "self-pay" or "cash-pay"); private insurance; public insurance (Medicaid and Medicare); or government delivered and financed health care. Various prescription drug programs are

managed by Pharmacy Benefit Managers (PBMs) and engage networks of pharmacies and providers to deliver prescription drugs. [See Attachment 3 in this report].

37. The payment for prescriptions through cash or self-pay by individuals was discussed in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 12] as follows:

Self-pay, or cash, prescriptions represent a shrinking part of the outpatient prescription market. In 1992, more than one-half (55.6 percent) of all outpatient prescriptions were self-pay. By 1997, self-pay prescriptions had shrunk to 29.1 percent and in 2002 and 2003 they represent less than 15 percent of outpatient prescriptions. The dramatic reduction in cash pay prescriptions has also greatly reduced the pharmacy's pricing flexibility. The pharmacy has some control over setting the price for cash pay prescriptions, but it has little control over the prices paid by public and private third party programs. Although mail order programs, private PBMs and drug discount cards all claim to compare their prices against usual and customary retail prices, the disappearance of the cash pay retail prescription market renders the concept of "usual and customary retail price" almost meaningless.

38. The payment for prescriptions by private third parties (e.g., insurance and managed care) was discussed in my report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 12] as follows:

The share of outpatient prescriptions covered in part, or in whole, by private third party programs has grown substantially over the past decade from 30.1 percent in 1992 to 73.0 percent in 2002 and 2003. Most of these third party prescriptions are managed through PBMs and networks of pharmacies that have contracted to participate in these networks. Most pharmacists report that PBMs have most of the negotiating power in these networks, especially given their growing market share and the dominance of a few large PBMs.

39. The payment for prescriptions through public third parties (e.g., Medicare and Medicaid) was discussed in my report to CMS titled [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 12-13] as follows:

The Medicaid program is the single largest third party program (public or private) for prescription drug coverage. In 1992, Medicaid paid for 14.3 percent of all outpatient prescriptions and by 1997 the Medicaid share had dropped to 11.7 percent. The Medicaid share of outpatient prescription(s) has grown again over the last five years to 13.0 percent of outpatient prescriptions. Medicaid recipients in some states may pay modest co-payments. However, under certain

circumstances if the patient can not pay the copay the pharmacy may still be required to dispense the prescription and the pharmacy may not be able to recover the lost copay from either the patient or the Medicaid program.

Part B of Medicare paid for approximately 4 percent of total prescription drug expenditures in 2002. Once the MMA prescription drug benefit is implemented (January 1, 2006), Medicare (Parts B and D) will become the single largest third party program easily surpassing the Medicaid program. Medicare Part B beneficiaries are currently responsible for 20 percent of the cost of their covered medication, a sum that may be a substantial burden in cases in which beneficiaries do not have other insurance.

40. Collectively, third party prescriptions (private and government, such as Medicaid) grew from 70% of the prescription dollars and 67% of the prescriptions in 1996 to 91% of the prescription dollars and 89% of the prescriptions in 2005. With the institution of the Medicare Part D prescription drug program in 2006, the public third party share of the source of payment for prescriptions had a substantial jump, with all third parties (private and public) now covering the vast majority (greater than 92%) of all prescriptions. [National Association of Chain Drug Stores (NACDS), *The Chain Pharmacy Industry Profile*, annual editions from 1998 to 2005. Data was from IMS Market View, as reported in Novartis Pharmacy Benefit Report for 1996 to 2001 and from NDC Health (a health care information company) from 2002 to 2006]. Conversely, the share of prescriptions paid for entirely by cash or the individual shrank to well under 10% of all prescriptions in 2006.

## V. OVERVIEW OF PHARMACEUTICAL PRICING

41. There have been a number of signals raising concern over drug prices in the pharmaceutical market in recent years (i.e., since 2001). These signals regarding pricing behaviors in the pharmaceutical market were succinctly described in my 2004 report to CMS that was titled *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices* [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, p. 2] as follows:

A number of signals in the market have raised concern about prescription drug prices and expenditures to the top of the public policy agenda. First, outpatient drug expenditures in both public and private programs have been growing at an annual rate of 15 to 20 percent since the mid-1990s—a rate that is more than double the rate of growth in total health spending (i.e., Medicaid total expenditures grew 7.7 percent per year from 1997 to 2000).<sup>4</sup> Second, prescription drugs are the fastest growing sector of Medicaid programs, which, in turn, are one of the largest segments of state spending at a time when states are facing record deficits.<sup>5</sup> Third, the prices paid for prescription drugs by the Medicaid and Medicare programs have come under question compared to the prices paid by other sectors of the market.<sup>6</sup> For example, most other government programs (i.e., the Veterans Administration, and the 340B program for federally qualified facilities) pay less for prescription drugs than do the Medicaid or Medicare Part B programs, even after accounting for rebates.<sup>7</sup> Fourth, there is evidence that drug manufacturers have ‘gamed’ the pricing policies of both Medicare Part B and the Medicaid drug rebate program in a manner that creates economic incentives that lead to increased rather than decreased drug expenditures.<sup>8,9,10</sup> Fifth, legislation to cover outpatient prescription drugs under

<sup>4</sup> Gencarelli, Dawn M., Medicaid Prescription Drug Coverage: State Efforts to Control Costs, National Health Policy Forum, George Washington University, NHPF Issue Brief No. 790, May 10, 2003.

<sup>5</sup> Lav, Iris J. and Johnson, Nicholas, “State Budget Deficits for Fiscal Year 2004 are Huge and Growing,” Center on Budget and Policy Priorities, revised January 23, 2003; accessed February 3, 2003, at <http://www.cbpp.org/12-23-02sfp.pdf>.

<sup>6</sup> US House of Representatives, Committee on Energy and Commerce, Subcommittee on Health and the Subcommittee on Oversight and Investigations, Hearing, September 21, 2001.

<sup>7</sup> Schondelmeyer, Stephen W. “Estimated Relative Price Compared to AWP for Prescription Drugs at Manufacturer Level,” Chart 4, p.10 as found in von Oehsen, William H., III, Ashe, Marice and Duke, Kathryn, *Pharmaceutical Discounts Under Federal Law: State Program Opportunities*, Public Health Institute, Pharmaceuticals and Indigent Care Program, Oakland, CA, May 2001.

<sup>8</sup> “2 Drug Makers to Pay \$875 Million to Settle Fraud Case,” New York Times, Oct. 4, 2001.

<sup>9</sup> “AstraZeneca Pleads Guilty in Cancer Medicine Scheme,” New York Times, June 21, 2003.

<sup>10</sup> “Bayer Agrees to Pay U.S. \$257 Million in Drug Fraud,” New York Times, April 17, 2003.

Medicare has recently been passed by the U.S. Congress and is set for an ambitious implementation schedule over the next year and one-half.<sup>11</sup>

42. The prescription drug market is characterized by “reverse, perverse economics” stemming from, *inter alia*, the following facts: (1) this is not a normal supply and demand market, (2) the vast majority of prescriptions are paid for by third party payers, and (3) different players in the system decide what medication is needed (the physician) and which particular medication is dispensed (the pharmacist), as well as which drug products are preferred (the PBMs), and all of these players are different from the ultimate payer (employer, government or individual) or the patient. There is little price transparency at most levels of the market. The third party reimbursement system has even led certain participants in the market to prefer the establishment and maintenance of high prices in various sectors of the market for their own benefit and to the detriment of the ultimate payer or patient.

43. Observation of prices in the pharmaceutical market requires an understanding of the elements, or attributes, that define a specific drug price term and an awareness of the sources of variation in price in the market.

#### **A. Elements and Attributes of Drug Pricing Terms**

44. There are several important and essential elements, or attributes, to any drug price that must be understood in order to know the meaning of a specific price for a specific drug product. These elements of a drug price were described in my report to CMS titled *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices* [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 13-14] as follows:

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<sup>11</sup> “Medicare Bills Would Add Drug Benefits: Prescription Drug Benefit Is Key To Biggest Changes in 38 Years,” Washington Post, June 27, 2003, p. A01.

\* ***list or transaction***: list prices are published by manufacturers; transaction prices stem from actual transactions and hence represent both the supply and the demand side of the market;

\* ***level of the market involved***: drug product transactions occur at different levels in the market such as the manufacturer, wholesaler, or provider (e.g., pharmacy, physician, hospital, etc.) levels;

\* ***classes of trade eligible for the price***: providers are grouped by each manufacturer into various classes of trade based on the structure of the pharmaceutical market (e.g., independent pharmacies, chain pharmacies, mail order pharmacies, long term care pharmacies, hospitals, physicians, etc) and the manufacturer's average selling price usually varies across classes of trade;

\* ***type of drug product***: drug products may be grouped by their patent and exclusivity status into three broad groups that have different pricing patterns such as single source (patent and exclusivity protected brands), innovator multiple source (off-patent brands), and non-innovator multiple source (generics or branded generics) drug products;

\* ***adjustments to price that have or have not been taken into account***: the invoice price for drug products may not reflect all adjustments to prices such as discounts, rebates, purchasing allowances or other forms of economic consideration;

\* ***source of the price information***: price information can be collected from different sources such as the manufacturer, wholesaler, provider, or a third party program;

\* ***effective time when price is available***: manufacturers determine when and how much the price of a drug product will change and the providers' costs are affected by price changes immediately upon implementation of a price change. The timing of when third party programs update their price reimbursement files (e.g., immediately or based on retrospective data) can have a substantial impact on providers; and

\* ***relationship to other prices***: AWP and WAC are primarily used as benchmark prices rather than as actual transaction prices, but most other types of prices, discounts, rebates, and methods of third party reimbursement are expressed in relationship to one of these benchmark prices (AWP or WAC).

## **B. Description of Key Drug Pricing Terms**

45. There are several key drug price terms commonly used in the prescription pharmaceutical market in the United States. Discussed here will be the terms: wholesale acquisition cost (WAC), average wholesale price (AWP), direct price (DP), earned discounts, and actual acquisition cost (AAC). These pricing terms as they have been used

in statute or regulation related to Medicaid, Medicare or other third party programs, as well as other drug pricing terms that serve more specialized roles, are discussed elsewhere in this report. These drug pricing terms in the context of 2004 were described in my report to CMS titled *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices* [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 14] as follows:

**Wholesale Acquisition Cost (WAC).** The Wholesale Acquisition Cost (WAC) is a list price used for invoices between drug manufacturers and wholesalers and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration. The WAC is set and published by drug manufacturers with an effective date and remains in effect until a change in price is published. Some drug manufacturers have other names for this price such as list price, catalog price, or book price. In the past decade, WAC was a term that typically included adjustments for discounts, rebates, purchasing allowances, or other forms of economic consideration. More recently, WAC has come to mean a list price before any form of price adjustment. WAC is closer to wholesaler's actual acquisition cost than is AWP. However, due to different levels of discounts across drug products and specific classes of trade, the WAC does not generally have a reliable relationship to the actual acquisition cost. Within a specific class of trade, WAC may have a consistent relationship with the actual acquisition cost for single source brand name (patented and exclusivity protected brands) drug products, but not for innovator multiple source (off-patent brands) or non-innovator multiple source (generic) drug products. If WAC is to be used to estimate a price from wholesaler to provider (i.e., pharmacy, physician, or others), an adjustment must be made to account for the wholesaler (or chain warehouse) operating cost and a reasonable profit.

**Average Wholesale Price (AWP).** The Average Wholesale Price (AWP) is a list price used for invoices between drug wholesalers and pharmacies or other appropriate drug purchasers and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration. The AWP is set directly, and published, by most drug manufacturers with an effective date and remains in effect until a change in price is published. Some drug manufacturers argue that they do not set the AWP, but instead either the wholesaler or the drug price databases set the AWP. Even when the AWP is actually calculated by a wholesaler or a drug price database, these sources typically calculate the AWP as a fixed percentage above the WAC (i.e., typically 20 or 25 percent above WAC for brand name drugs) so that, in effect, by setting the WAC the drug manufacturer also sets the AWP for a drug product. AWP has been a term that typically does not include adjustments for discounts, rebates, purchasing allowances, or other forms of economic consideration. The AWP is typically 20 to 25 percent above the WAC for brand name drugs, but may be considerably higher (20 to 70 percent) than WAC for

generic drugs. Because of different levels of discounts across drug products and specific classes of trade, the AWP does not generally have a reliable relationship to the actual acquisition cost. Within the retail class of trade, AWP may have a consistent relationship with the actual acquisition cost for single source brand name (patented and exclusivity protected brands) drug products, but not for innovator multiple source (off-patent brands) or non-innovator multiple source (generic) drug products.

**Direct Price (DP).** The Direct Price (DP) is a list price used for invoices between drug manufacturers and pharmacies or providers and is typically used as a benchmark for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration. The DP is set and published by drug manufacturers with an effective date and remains in effect until a change in price is published. Many drug manufacturers have a wholesale only policy and do not sell directly to pharmacies or providers, while other drug firms establish a direct price and do sell drug product directly. Direct purchases are often subject to minimum order quantities and, therefore, direct purchases may not be practical or economically efficient for many purchasers.

Certain direct purchasers (i.e., physicians, but typically not pharmacies) may benefit from delayed invoice dating (e.g., payment is not due for 60 or 90 days) from the manufacturer. The DP for some manufacturers is the same as the WAC, while for others the DP may be slightly higher (by 3 to 5 percent) than WAC. Because of different levels of discounts across drug products and specific classes of trade, the DP does not generally have a reliable relationship to the actual acquisition cost. Within the retail class of trade, DP may have a consistent relationship with the actual acquisition cost for single source brand name (patented and exclusivity protected brands) drug products, but not for innovator multiple source (off-patent brands) or non-innovator multiple source (generic) drug products. However, use of direct price to estimate pharmacy or provider acquisition cost must take into account the added cost of acquisition. A larger share of generic drugs, than of brand-name drugs, is sold direct from the manufacturer. Because of different levels of discounts, the DP does not have a reliable relationship to the actual acquisition cost, in general, or for specific classes of trade.

**Earned Discounts.** Earned discounts are transactional discounts based on efficient business practices of the pharmacy or physician purchasing drug products from either a wholesaler or a drug manufacturer. The earned discount is usually expressed in terms such as '2-10 Net 30', meaning 2 percent discount off of the total invoice amount if paid within 10 days and the full invoice amount is due if paid between 11 and 30 days. Earned discount terms are set by the wholesaler or the manufacturer and are usually stated on the invoice. In some cases, manufacturers offer substantially greater delayed invoice payment to certain classes of trade (e.g., direct physician purchasers) that allow the purchaser to sell and collect for the drug product before the payment to the manufacturer is due (e.g., payment is not due for 60 or 90 days). These greatly delayed invoice terms would not typically be called 'earned discounts'. Different levels of 'earned discounts' and 'other delayed term discounts' are available to different classes of trade. The earned discounts will usually have a reliable relationship to actual acquisition cost, but not necessarily to AWP or WAC. The treatment of

earned discounts in estimating actual acquisition costs of a pharmacy or provider should be consistent with the actual payment terms of a given third party when reimbursing pharmacies or providers.

***Actual Acquisition Cost (AAC).*** The Actual Acquisition Cost (AAC) is a transaction price used to describe the price paid by a pharmacy or provider when purchasing a drug product from either a drug manufacturer or wholesaler. The invoice price and all on-invoice, as well as off-invoice, adjustments for discounts, rebates, purchasing allowances, or other forms of economic consideration are taken into account. This price is the appropriate conceptual basis for the payment policy.

The AAC is set by the drug manufacturer, but, historically, has not been published or made public. Some drug manufacturers may have a variety of terms for specific discounts that are based on class of trade, volume of purchase, market share movement, preferred formulary status, terms of payment, bundling of products, and other criteria. AAC is meant to be the net price after all forms of discount, rebate, purchasing allowances or any other forms of economic consideration have been taken into account. Arguably the discounts that contribute to AAC are considered proprietary and confidential by drug manufacturers. Consequently, the relationship of AAC to either AWP or WAC is not predictable from public data sources in general, or for specific classes of trade. For single source brand name drugs that do not typically have discounts beyond on-invoice 'earned discounts', the AAC may have a reasonably predictable relationship to AWP or WAC.

46. The definition and understanding of these, and certain other drug price terms, should be viewed in historical perspective and in context. As noted above, for example, in the context of the compendia that have been used as public sources of pricing information, AWP came to be used as a reference to the price on invoices from the wholesaler to the pharmacy. I am also aware that Judge Saris has examined the meaning of the term AWP in the Medicare context and determined that the term should be given its plain meaning in accordance with established principles of statutory construction. The historical context should also be considered, for example, in the early 1990s, a report to HCFA (now CMS) on the adequacy of reimbursement rates to pharmacies provided a definition of key drug pricing terms. [Adams, Kathleen and David H. Kreling, *Assessment of Adequacy of Reimbursement Rates to Pharmacies and Its Impact on the*

Access to Medication and Pharmacy Services by Medicaid Recipients, HCFA Contract No. 500-92-0024, Delivery Order No. 3, August 25, 1993, p.4].

47. This 1993 report to HCFA on pharmacy reimbursement defined the following drug price terms:

- \* Actual Acquisition Cost (AAC) – Pharmacist's net payments made to purchase a drug from any source (e.g., manufacturer, wholesaler) net of discounts, rebates, etc.
- \* Estimated Acquisition Cost (EAC) – An estimate of pharmacies' actual acquisition costs that are made by the States and other third-party payers.
- \* Maximum Allowable Cost (MAC) – A maximum dollar amount for which the pharmacist is reimbursed for selected products.
- \* Average Manufacturer's Price (AMP) – The average price paid by wholesalers to manufacturers for products to be distributed to retailers.
- \* Average Wholesale Price (AWP) – The manufacturer's suggested wholesale price to the retailer which is listed in either the Red or Blue Book.
- \* Wholesale Acquisition Cost (WAC) – The wholesaler's net payment made to purchase a drug product from the manufacturer, net of purchasing allowances and discounts.

[Adams, Kathleen and David H. Kreling, Assessment of Adequacy of Reimbursement Rates to Pharmacies and Its Impact on the Access to Medication and pharmacy Services by Medicaid Recipients, HCFA Contract No. 500-92-0024, Delivery Order No. 3, August 25, 1993, p.4].

48. In this 1993 report to HCFA, the term 'actual acquisition cost' had essentially the same meaning as it did in the 2004 report to CMS. That is, AAC represents the net transaction price paid by a pharmacy or provider. Similarly, the AWP as described by the authors of both reports is a price reported, directly or indirectly, by the drug manufacturer as the suggested price from the wholesaler to the retailer. The relationship of AWP to actual transaction prices, however, has not been consistent over time or across types of drug products, such as the use of this term with respect to brand name and generic drug products.

49. Notably, the definition of WAC appears to have changed over time. In 1993 WAC was, or was believed to be, "the wholesaler's net payment made to purchase a drug product from the manufacturer, net of purchasing allowances and discounts." [Adams,

Kathleen and David H. Kreling, Assessment of Adequacy of Reimbursement Rates to Pharmacies and Its Impact on the Access to Medication and Pharmacy Services by Medicaid Recipients, HCFA Contract No. 500-92-0024, Delivery Order No. 3, August 25, 1993, p.4]. By 2004, however, WAC had come to be viewed as a benchmark price for all classes of trade without adjustment for discounts, rebates, purchasing allowances, or other forms of economic consideration [MMA; Pub.L. 108-173].

50. The term 'estimated acquisition cost' was defined in the 1993 study for HCFA as a price intended to be an estimate of the pharmacy's actual acquisition cost. The Medicaid program has consistently defined estimated acquisition cost as a price concept that provides a method to estimate the 'actual acquisition cost' to the pharmacy or provider, as described in a later section. This consistent definition of 'estimated acquisition cost' as an estimate of the pharmacy's actual acquisition cost was first defined by Medicaid as far back as 1977 and continues to be defined in the same way as recently as 2006.

### **C. Definition and Determination of Estimated Acquisition Cost (EAC)**

51. Actual drug transaction prices in the market have not been, and still are not, readily available to third party payers, including government entities, on a routine basis, and audits to gather that information are extremely expensive and time-consuming and frequently result in outdated and incomplete information. Consequently, the development of a price database for payment and reimbursement of prescription drugs requires some means of estimating acquisition cost for drug products on an ongoing basis.

52. The term “estimated acquisition cost” (EAC) was created by Medicaid for use in the reimbursement of prescription drugs. [42 C.F.R. § 447.301, 10-1-01 Edition]. The estimated acquisition cost was developed as a way to simplify payment for prescriptions in a manner that was consistent with the Medicaid program’s intent to pay the actual acquisition cost for a given prescription drug or as close to the actual acquisition cost as is feasible. Determining the actual acquisition costs of every prescription would require auditing literally tens of thousands of prescription drugs on the market and the price of each drug product to each pharmacy for every time a purchase is made. Such an audit of actual acquisition costs would be extremely difficult, complex, and very time-consuming and expensive. Use of audited actual acquisition costs was simply not feasible.

53. The Medicaid program chose to base prescription payments on “estimated acquisition cost.” The intent and definition of estimated acquisition cost dates as far back as 1977 as described in an HHS document titled, “Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC).” This HHS memo to state Medicaid directors stated “The intention of the final Medicaid regulations on drug reimbursement is to have each state’s estimated acquisition cost as close as feasible to the price generally and currently paid by the provider. The states are, therefore, expected to set their ingredient cost levels as close as possible to actual acquisition cost.” [“HHS Action Transmittal, HCFA-AT-77-113 (MMB), December 13, 1977. Subject: Title XIX, Social Security Act: Limitation on Payment or Reimbursement for Drugs: Estimated Acquisition Cost (EAC).” as reproduced in National Pharmaceutical Council (NPC), *Pharmaceutical Benefits Under State Medical Assistance Programs*, 1983, p. 14].

54. The term “estimated acquisition cost” (EAC) was further defined as “the price generally and currently paid by providers for a particular drug in the package size most frequently purchased by providers.” [NPC, *Pharmaceutical Benefits*, 1991, p. 51.; 1994, p.14; 1999, p.4-55]. This description of EAC was reported in the Medicaid compendium titled *Pharmaceutical Benefits Under State Medical Assistance Programs* (NPC Medicaid Book) and published by the National Pharmaceutical Council (NPC). This description of EAC, emphasizing that this term is supposed to represent a price that is “as close as feasible to the price generally and currently paid by the provider” or a similar statement, has been reported in every annual volume of the NPC Medicaid Book from 1979 to 2005-2006. Roxane, an affiliate of BIPI, was aware of, and had access to, this publication since BIPI has been a sponsoring member of the National Pharmaceutical Council since 1983 or before. [NPC, *Pharmaceutical Benefits*, annual volumes, 1983 to 2006, membership list on back cover]. Dey was also aware of, and has referenced, the National Pharmaceutical Council publications on Medicaid program reimbursement in internal documents and communications as far back as 1995. (Memo from Dey Laboratories to Beth Raider, Price Alert and Pharmacy Blue Book Update, May 30, 1995, attachment “Medicaid Rx Reimbursement Report, Drug Topics, February 6, 1995, Source: National Pharmaceutical Council.)

55. Because transaction prices were not consistently and publicly available and the reported AWP, WAC, and/or DP were the only prices consistently available for all, or virtually all, drug products, most public and private third party programs used manufacturer-reported AWP, WAC, and/or DP prices, or adjusted versions of these prices, as their means of estimating acquisition cost for drug products. In other words,

most private third party and government payers set their payment formulae for estimating drug product costs as either a certain percent discount off of wholesale to retail prices (AWP) or a certain percent above the prices from manufacturers to wholesalers (WAC).

56. The potential methods for states, or CMS, to estimate or determine market prices for prescription drugs were evaluated in a research project I conducted with colleagues from Abt Associates, Inc. for the Centers for Medicare & Medicaid Services in 2004. [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 1-70 plus Appendices].

57. In conducting our study of methods to estimate acquisition costs for pharmaceuticals, we set forth several criteria that would assist in determining the validity and reliability of the estimation method. Ideally, the method used for determining “estimated acquisition cost” should produce cost information for each drug product with prices that are: accurate and reliable, generally and widely available, current and up-to-date, transparent and accessible, adequate compensation to providers and pharmacies, incentives for pharmacies and providers to supply drugs, and incentives for key parties to provide data. The nature of each of these criteria, as discussed in my 2004 report to CMS [Schondelmeyer and Wrobel, *Medicaid and Medicare Drug Pricing*, 2004, pp. 18-19], is discussed briefly:

**Accurate and Reliable**

The Medicaid and Medicare programs should have access to accurate and reliable information regarding the actual acquisition costs for prescription drugs for each channel of distribution. Based on such accurate and reliable cost data, these programs may decide that the payment rate to pharmacies or physicians should include a percent markup on brand name drug product costs, and an even greater markup for generic drugs, but this practice should be an explicit decision of the policy maker and not an implicit and hidden factor left in the control of the pharmaceutical manufacturer. In this context, ‘accuracy’ concerns the degree to which the price used in payment policy is close to, or the same as, the amount actually paid by a pharmacy or physician for a given drug product. ‘Reliability’